IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SPRING PHARMACEUTICALS, LLC, Plaintiff, *v.* RETROPHIN, INC.; MARTIN SHKRELI; MISSION PHARMACAL COMPANY; ALAMO PHARMA SERVICES, INC.; and EVERSANA LIFE SCIENCE SERVICES Defendants.	)	Civil Action No. 2:18-cv-04553-JCJ

[PROPOSED] ORDER GRANTING RETROPHIN, INC.'S MOTION TO DISMISS SPRING PHARMACEUTICALS, LLC'S AMENDED COMPLAINT

AND NOW, this _____ day of _____, 2020, upon consideration of Defendant Retrophin, Inc.'s Motion to Dismiss Spring Pharmaceuticals, LLC's Amended Complaint, and any oppositions and replies thereto, and there being good cause shown, it is hereby:

ORDERED that Defendant Retrophin, Inc.'s Motion to Dismiss is GRANTED and Spring Pharmaceuticals, LLC's Amended Complaint, as to Defendant Retrophin, Inc., is hereby DISMISSED WITH PREJUDICE.

BY THE COURT:

_____
J. CURTIS JOYNER, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SPRING PHARMACEUTICALS, LLC, Plaintiff, *v.* RETROPHIN, INC.; MARTIN SHKRELI; MISSION PHARMACAL COMPANY; ALAMO PHARMA SERVICES, INC.; and EVERSANA LIFE SCIENCE SERVICES Defendants.	)	Civil Action No. 2:18-cv-04553-JCJ ORAL ARGUMENT REQUESTED

RETROPHIN, INC.'S MOTION TO DISMISS
SPRING PHARMACEUTICALS, LLC'S AMENDED COMPLAINT

Defendant Retrophin, Inc., pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure and the Local Rules of this Court, respectfully requests that the Court dismiss Spring Pharmaceuticals, LLC's Amended Complaint with prejudice on the grounds set forth in the accompanying memorandum of law.

Dated: April 1, 2020

Respectfully Submitted,

s/ Richard E. Coe

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CERTIFICATE OF SERVICE

I certify that on April 1, 2020, I filed this document on the Court's docket using the Court's CM/ECF system. Based on the Court's records, all counsel of record were served with a copy of the foregoing document by electronic means.

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SPRING PHARMACEUTICALS, LLC, Plaintiff, *v.* RETROPHIN, INC.; MARTIN SHKRELI; MISSION PHARMACAL COMPANY; ALAMO PHARMA SERVICES, INC.; and EVERSANA LIFE SCIENCE SERVICES Defendants.	)	Civil Action No. 2:18-cv-04553-JCJ

MEMORANDUM IN SUPPORT OF RETROPHIN, INC.'S MOTION TO DISMISS SPRING PHARMACEUTICALS, LLC'S AMENDED COMPLAINT

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Defendant Retrophin, Inc. ("Retrophin") respectfully submits this Memorandum of Law in Support of its Motion to Dismiss the Amended Complaint filed by Spring Pharmaceuticals, LLC ("Spring"), pursuant to 12(b)(6) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

Spring, claiming to be a generic pharmaceutical company that was delayed from entering the market for generic Thiola, readily admits that it has *never* produced any drug—generic or otherwise. It was formed just weeks before it was allegedly excluded from the market. It does not claim to have any employees and does not allege how much funding it has raised (if any). Its founder, "CEO," and sole member is an antitrust lawyer from Spring's original litigation counsel.[1] In short, Spring bears every indication of being nothing more than a legal vehicle created to pursue this litigation.

Regardless, the Amended Complaint should be dismissed, this time with prejudice, because Spring fails (again) to meet the well-established threshold requirement to bring an antitrust case: antitrust standing. In dismissing Spring's original complaint for lack of antitrust standing, the Court held that Spring, which has not entered the market, failed to plead "intention and preparedness" to enter the market because "it has not adequately plead that it has taken sufficient affirmative steps to enter the market." (Order 39, Dec. 11, 2019, ECF No. 96, (hereinafter "Order")). In particular, the Court noted that it is "unclear" whether Spring has established sufficient manufacturing and distribution networks or whether it has even "started the process" of securing other contracts that would be needed to obtain FDA approval. (*Id*. 40-41). The Amended Complaint fails to correct these fatal deficiencies and, if anything, confirms that Spring never had the intention and preparedness to enter the market.

[1] Charles Li was an antitrust associate at Winston & Strawn. Winston & Strawn withdrew as counsel to Spring after this Court dismissed Spring's original complaint.

As the Court held in dismissing the original complaint, in order to show "intent and preparedness," a plaintiff must show: "(1) that plaintiff had the background and experience to enter the market; (2) that plaintiff had the financial ability to enter the market; and, (3) most importantly, that plaintiff took affirmative actions to enter the market." (*Id*. 35). Spring fails on all three grounds.

First, there can be no serious question that Spring does not have the background or experience to enter the market. It admits that it has never produced a pharmaceutical product and its founder, CEO, and sole member is an antitrust lawyer. Nor does it allege that it has any employees, much less any employees with relevant background or experience.

Second, Spring fails to establish that it has the financial ability to enter the market. It claims it receives "operational funding" from an unnamed investor, although it does not say how much. It claims its CEO invests "personally," but likewise fails to quantify that investment. And it points to a non-binding "letter of intent" from an entity in China but fails to allege that the entity has in fact provided any funding. Those allegations come nowhere close to establishing that Spring has the financial ability to develop, test, obtain approval for, manufacture, and distribute a drug.

Third, Spring fails to plead that it took "affirmative actions" to enter the market. Like the original complaint, the Amended Complaint pleads that Spring reached an agreement with a contract development and manufacturing organization ("CDMO") and a "consultant," but does not allege that at the time it was allegedly prevented from entering the market, it had entered into contracts to perform many other functions that would be required to bring the drug to market, or even that it had "started the process." Rather, it alleges that it "will engage", "intends to contract with", and "intends to use" various vendors, most of which it does not identify. Indeed, Spring fails to allege that, even to this day, it has lined up someone to perform the bioequivalence testing that it

originally claimed it needed to do (and claimed it was prevented by Defendants from doing) in order to obtain FDA approval.

Even if Spring could meet the threshold requirement of antitrust standing (and it plainly cannot), Spring's claims would still fail for the following reasons.

Spring does not adequately plead a monopolization claim under Section 2 of the Sherman Act. Spring alleges that Retrophin's alleged failure to respond to a request for samples of Thiola prevented its entry into the market. But the law does not require companies to cooperate with their rivals, and the allegations in the Amended Complaint do not fall within the narrow exception to this rule, articulated in *Aspen Skiing*, which the Supreme Court has held marks the "outer limit" of Section 2 liability.

Spring also fails to plead an unlawful agreement as required to sustain its unlawful restraint of trade claims under Section 1 of the Sherman Act and its conspiracy to monopolize claims under Section 2 of the Sherman Act. Its attempt to rely on standard licensing and distribution contracts to allege an anticompetitive conspiracy fails as a matter of law. Moreover, even if the contracts were "conspiracies" under the Sherman Act, Spring has failed to overcome the presumption that such contracts are lawful.

Finally, Spring's state law claims fail for the same reasons its federal antitrust claims fail, as the Pennsylvania Supreme Court has stated that it will look to federal antitrust decisions in applying common law rules against allegedly unreasonable restraints of trade.

FACTUAL BACKGROUND

A. Retrophin and Thiola

Defendant Retrophin is a biopharmaceutical company that develops and commercializes treatments for rare diseases, including Thiola, an FDA-approved treatment for cystinuria. (Am. Compl. ¶¶ 2, 42). Cystinuria is a rare genetic disease—affecting approximately 33,000 Americans—that causes painful and recurring kidney stones. (*Id.* at ¶¶ 95-96). For some patients suffering from cystinuria, drugs like Thiola offer relief. (*Id.* at ¶ 97).[2]

In addition to making drugs for rare diseases available for patients who need them, Retrophin re-invests revenue from its commercialized pharmaceutical portfolio to fund research and development of novel pharmaceutical therapies for other rare diseases that have traditionally been ignored by the pharmaceutical industry.[3] For example, in 2019, Retrophin invested $140 million (approximately 80 percent of its net product sales) in research and development, generating a net loss of $146 million.[4]

In 2014, Retrophin acquired an exclusive license from Mission Pharmacal ("Mission") to market Thiola. (Am. Compl. ¶ 7). Notably, although Thiola is not patent-protected, no manufacturer has ever developed a generic version, (*id.* at ¶ 2), likely because of the small

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[2] In addition to Thiola (tiopronin), Cuprimine (penicillamine) and Depen (a branded generic of penicillamine) are other FDA-approved pharmaceutical treatments indicated for cystinuria. *See* Retrophin Annual Report (Form 10-K), p. 8, (Feb 24, 2020), https://www.sec.gov/Archives/edgar/data/1438533/000143853320000004/0001438533-20-000004-index.htm. A court is permitted to take judicial notice of facts that are capable of being "accurately and readily determined" on a motion to dismiss. Federal Rule of Evidence 201(b)(2). Therefore, courts will often take notice of materials produced by or filed with government agencies. *See, e.g.*, *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (taking judicial notice of SEC filings); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 (E.D. Pa. 2003) (taking judicial notice of materials published on FDA website).

[3] *Supra* n. 2, Retrophin Annual Report (Form 10-K), pp. 5-6, 8 (Feb 24, 2020).

[4] *Id*. at F-5.

population affected by cystinuria, coupled with the degree of investment necessary to adequately distribute the product and provide the necessary support to the patients with this rare disease. Indeed, before Retrophin acquired the rights to Thiola, the drug was on the FDA's drug shortage list.[5] Retrophin immediately shored up the Thiola supply, allowing cystinuria patients to reliably obtain the drug therapy they need.[6] Retrophin also invested, and continues to invest, heavily in practitioner and patient education, awareness, and support, largely through its direct-to-patient specialty pharmacy distribution system run through Eversana.[7] Retrophin, through Eversana, provides "comprehensive patient support services. . . a case managed approach to patient education, insurance verification and reimbursement support, co-pay and other financial assistance for eligible patients, monitoring and support of adherence, and 24/7 access to pharmacist counseling."[8] [9]

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[5] Retrophin Current Report (Form 8-K) (Apr. 11, 2016), https://www.sec.gov/Archives/edgar/data/1438533/000119312516537256/d148896d8k.htm.

[6] *Id*.

[7] *Supra* n. 2, Retrophin Annual Report (Form 10-K), p. 12 (Feb. 24, 2020).

[8] *Id*.

[9] The Amended Complaint relies heavily on a 2016 Senate Report that followed an investigation into four companies and their drug products, including the statements of Retrophin's former CEO, Martin Shkreli. Such reliance is misplaced in light of the Report's conclusion that "there is a difference between the Retrophin run by Mr. Shkreli, and the Retrophin after the departure of Mr. Shkreli. . . it has made considerable investments in patient assistance for Thiola and appears to have renounced Mr. Shkreli' s business model." *See Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*" (Dec. 2016), p. 42, https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf. Therefore, Spring's alleged connections between the statements by Mr. Shkreli and Retrophin's business conduct years later are disingenuous and purposefully misleading. In addition, the congressional testimony about the investigation that Spring cites refers to another company (not Retrophin) and to another drug (not Thiola). (Am. Compl. ¶ 109; *see also* ¶ 126).

In June 2019, the FDA approved Mission's new drug application ("NDA") for a new formulation of Thiola IR, called Thiola EC.[10] (Am. Compl. ¶ 67). The new formulation has advancements over the original formulation, including that it reduces pill burden and can be taken with or without food, making dosing and compliance easier for patients.[11] Retrophin has not removed Thiola IR from the market (Am. Compl. ¶¶ 67-68) and does not intend to do so.[12]

B. Spring Is Formed as a Vehicle to File this Litigation.

Spring was formed in November 2017. (Am. Compl. ¶ 16). Its founder, CEO, and sole member is Charles Li (*id*. at ¶ 90), who was an associate at Winston & Strawn (Spring's original litigation counsel).[13] On January 19, 2018, shortly after Spring's formation, it faxed a letter to a number listed on Retrophin's Thiola web portal, claiming that Spring was a "generic pharmaceutical company developing a generic version of Thiola" that wanted to purchase samples of Thiola for the purposes of conducting bioequivalence studies. (*Id*. at ¶¶ 75-76). In June 2018, Spring sent a letter to Retrophin again purporting to be a generic drug company that wanted to purchase samples of Thiola. (*Id*. at ¶ 78).

Spring does not allege that it has ever engaged in *any* business and admits that it has never developed, marketed, or distributed a pharmaceutical product. (*Id*. at ¶ 71) (admitting that a generic version of Thiola will be Spring's "first product"). Spring does not claim to have any assets,

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[10] For purposes of this brief, we refer to the original formulation of Thiola as "Thiola IR," the new formulation of Thiola as "Thiola EC," and the product generally as "Thiola."

[11] *Supra* n.2, Retrophin Annual Report (Form 10-K), p. 8, (Feb 24, 2020).

[12] Retrophin Quarterly Report (Form 10-Q), p. 21, (Oct. 30, 2019), https://www.sec.gov/Archives/edgar/data/1438533/000143853320000004/0001438533-20-000004-index.htm.

[13] Jialue "Charles" Li's archived attorney profile from the website of Winston & Strawn as of October 22, 2016, accessed through https://web.archive.org/ (ECF No. 42-3, Ex. D).

although it claims that Mr. Li has made unquantified "personal" investments and that it receives unquantified operational investments from a source it does not identify. (*Id*. at ¶ 90). It alleges it holds a document that it purports is a "letter of intent" from an entity in China. (*Id*.). The "letter of intent" states it "does not represent an enforceable legal contract" and further states that even after Spring received the samples, the entity would perform a due diligence review before deciding whether to invest. (*Id*. at ¶ 90 and Ex. K). Despite having had the samples for six months, Spring does not allege that the Chinese entity has made any investment or even conducted due diligence.

Spring does not allege that it and Retrophin had any interaction other than the two letters noted above. (*Id*. at ¶¶ 75-79). Retrophin did not hear from Spring again until Spring initiated the current litigation in October 2018. (ECF No. 1).

C. Defendants File Motions to Dismiss and the Court Orders Discovery.

Retrophin filed a Motion to Dismiss pursuant to 12(b)(1) and 12(b)(6) on January 15, 2019, arguing that Spring lacked Article III standing, as well as the intention or preparedness to enter the market for Thiola as required to show antitrust injury. (ECF No. 42-01).

On April 10, 2019, this Court ordered that Defendants had ninety days to take discovery on the issue of Spring's constitutional standing. (ECF No. 52). After the close of discovery, on August 21, 2019, Spring filed a Supplemental Brief Establishing Article III Standing and in Opposition to Defendant's Motions to Dismiss. (ECF No. 81). Defendants filed their responses on September 20, 2019. (ECF Nos. 88, 89, and 91).

D. Retrophin Sells Spring Thiola Samples, Spring's Complaint Is Dismissed, and Spring Files an Amended Complaint.

While the litigation was ongoing, in June 2019, Retrophin offered to sell Spring the samples in exchange for dropping this litigation. (Am. Compl. ¶ 69). Spring declined. (*Id.*). On August 5, 2019, while denying that Spring is a legitimate potential competitor and without conceding any

obligation to do so, Retrophin offered to sell Spring samples at market price for use in bioequivalence studies—the explicit purpose for which Spring claims it sought the samples (*see, e.g.*, *id.* at ¶¶ 72-73, 76, 107)—rather than for other commercial purposes such as transfer or resale. (*Id.* at ¶ 69, n. 45). Spring again refused, stating it would not accept any restriction. (*Id.*)

In September 2019, still denying Spring's legitimacy and any legal obligation to do so, Retrophin agreed to sell Spring samples without any conditions or restrictions. (*Id*. at ¶ 66). On October 8, 2019, after receipt of payment from Spring, Retrophin shipped the requested volume of samples to Spring through its distribution center and specialty pharmacy, Eversana. (*Id*. at ¶¶ 66, 80). Spring does not allege that over the following two months, it did anything with the samples it had claimed it needed or that it took any other steps to develop a generic tiopronin. (*Id*. at ¶ 84 and Ex. F).

On December 11, 2019, the Court dismissed all claims in Spring's original complaint, ruling that Spring had not alleged that it had taken "sufficient affirmative steps" to enter the market and, therefore, lacked antitrust standing, and granted leave to amend. (Order 40-41).

Eight days later, on December 19, 2019, Spring and its contract CDMO held a "kick-off" meeting. (Am. Compl. ¶ 84 and Ex. F).

Although it has now been in possession of samples for six months, Spring does not allege that it has taken any affirmative steps to enter the market. Rather, it alleges that it has "identified" the "ingredients" that will be used in the product (information that is readily available on the internet[14]), "outlined relevant analytical methods" and "developed a detailed timeline." (*Id.* at ¶ 84).

On February 10, Spring filed its Amended Complaint.

[14] *See, e.g.*, Am. Compl. ¶ 86 n. 64, citing Draft Guidance on Tiopronin, U.S. FOOD & DRUG ADMIN. 1 (Jul. 2017), https://www.accessdata.fda.gov/drugsatfda_docs/psg/Tiopronin_oral%20tablet_NDA%2019569_RC05-17.pdf.

ARGUMENT

As set forth below, Spring's claims fail because, first and foremost, Spring has wholly failed to cure the failure of its original complaint to establish antitrust standing. Even if it had antitrust standing (and it does not), the Amended Complaint should be dismissed because Spring fails to adequately allege a monopolization claim, a conspiracy claim, or a state law claim.

A. Spring Lacks Antitrust Standing.

A plaintiff cannot state a claim under the federal antitrust laws unless it establishes antitrust standing, which requires that the plaintiff adequately allege that it has "suffered antitrust injury." *Ethypharm SA France v. Abbott Labs.*, 707 F.3d 223, 233 (3d Cir. 2013); *In re Wellbutrin XL Antitrust Litig*., 868 F.3d 132, 164 (3d Cir. 2017); *see also Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.,* 429 U.S. 477, 489 (1977); *Roxane Labs. v. SmithKline Beecham Corp.*, 2010 WL 331704 at *2 (E.D. Pa. 2010) ("As part of showing antitrust standing, a private plaintiff must demonstrate injury-in-fact or causation.").[15]

To show that it has suffered "antitrust injury," a plaintiff must plead that the defendant caused injury to its "business or property." 15 USC § 15; Order 33 (citing *Roxane*, 2010 WL 331704 at *2); *see also City of Pittsburg*, 147 F. 3d at 265 ("Determining whether antitrust injury

[15] The Supreme Court has articulated factors that should be considered in deciding whether a complainant has antitrust standing: "(1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages." *Ethypharm*, 707 F.3d at 232-33 (citing *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519 (1983)). "[A]ntitrust injury, is a necessary but insufficient condition of antitrust standing." *Id*. (citation and quotation omitted); *see also City of Pittsburg v. West Penn Power Comp*., 147 F. 3d 256, 265 (3d Cir. 1998). If it is lacking, the other factors need not be addressed. *Id.* at 265 ("If antitrust injury is not found, further inquiry is unnecessary.").

is present necessarily involves examining whether there is a causal connection between the violation and the alleged injury."); *Ethypharm*, 707 F.3d at 237 (finding that plaintiff "did not suffer antitrust injury because it does not and indeed cannot compete" and "[a]s a result, [plaintiff] lacks antitrust standing"); *see also City of Pittsburg*, 147 F. 3d at 267 ("Without demonstrating that there was competition, a plaintiff cannot show that the defendants' actions have had or will have anticompetitive effects.").

Potential competitors that have not been injured in an existing "business or property" can demonstrate antitrust injury *only if* they sufficiently plead they had the "intention and preparedness" to enter a market at the time of the allegedly anticompetitive conduct, and would have done so but for such conduct. *Triangle Conduit & Cable Co. v. Nat'l Elec. Prod. Corp*., 152 F.2d 398, 399 (3d Cir. 1945) (The antitrust laws have "the limited purpose of affording compensation to those who have at least the intention and preparedness of engaging in a designated business and who are actually injured in their business or property by an unlawful act."); *Roxane*, 2010 WL 331704 at *3 ("[P]laintiff who was a 'potential' competitor during the time of the alleged unlawful behavior—in other words, a competitor who had not yet entered the market—must demonstrate intention and preparedness to enter the market in order to show injury."); *Brotech Corp.*, *v .White Eagle Int'l Techs. Grp., Inc*., 2004 WL 1427136 at *5 (E.D. Pa. 2004) ("[C]ourts require a 'potential' competitor to demonstrate both its intention to enter the market and its preparedness to do so.") (citation omitted).

This is because, as this Court articulated in *Roxane*, "[i]f a plaintiff was unprepared to enter the market, then the defendant's behavior was not a but-for cause of plaintiff's inability to enter the market." 2010 WL 331704 at *3; *see also Out Front Prods., Inc. v. Magid*, 748 F.2d 166, 170 (3d Cir. 1984) (If a plaintiff cannot show it was "poised and ready to enter the market" "there is unlikely

to be any plausible evidence to show that defendants impeded this effort. Certainly, the law will not countenance a dormant plaintiff who springs into action only when it is time to file suit.").

This standard enables courts to distinguish amongst the otherwise infinite number of possible plaintiffs and to prevent treble recovery by opportunistic plaintiffs with speculative claims or seeking windfall recoveries. Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (hereinafter Areeda & Hovenkamp, *Antitrust Law*) ¶¶ 349, 392 ("The preparedness hurdle . . . precludes opportunists from filing antitrust damage claims when they actually had no prior intention of entering the market in question"; "Refusing either to insulate wrongdoers from private attack or to grant treble damage windfalls to all nascent firms claiming exclusion, the courts entertain damage claims for precluded entry, but not too readily"; "The nascent firm's claim has proved troubling…plaintiffs in the hundreds could say they would have entered.").

"In order to show 'intention and preparedness,' the plaintiff must prove: (1) that plaintiff had the background and experience to enter the market; (2) that plaintiff had the financial ability to enter the market; and, (3) *most importantly*, that plaintiff took affirmative actions to enter the market." (Order 35 (emphasis added) (citing *Roxane*, 2010 WL 331704 at *3)); *see also Brotech*, 2004 WL 1427136 at *5 (On a motion to dismiss, "[t]he following factors are considered to be sufficient indicia of preparedness to enter the market: adequate background and experience in the new field, sufficient financial capability to enter it, and the taking of actual and substantial affirmative steps toward entry, such as the consummation of relevant contracts and procurement of necessary facilities and equipment.") (internal quotations omitted). "A simple hope or expectation to enter a business is insufficient." *DeGregorio v. Segal*, 443 F. Supp. 1257, 1262 (E.D. Pa. 1978); *see also Bourns v. Raychem*, 331 F. 3d 704, 712 (9th Cir. 2003) (finding plaintiff lacked antitrust

standing because plaintiff was a "bystander who was pawing the ground" only "wishing" to enter the market.).

Finally, the plaintiff must demonstrate that it had the intention and preparedness to enter the market *at the time of the allegedly anticompetitive conduct*. *Roxane*, 2010 WL 331704 at *3 ("A plaintiff who was a 'potential' competitor *during the time of the alleged unlawful behavior*—in other words, a competitor who had not yet entered the market—must demonstrate intention and preparedness to enter the market in order to show injury[.]") (emphasis added). Accordingly, Spring must establish its intention and preparedness to enter the market before October 2019 (*i.e.*, during the period of the allegedly anticompetitive conduct—before it received samples from Retrophin).

The Ninth Circuit in *Bourns v. Raychem* explains this legal requirement in detail. 331 F. 3d. 704 (9th Cir. 2003). In finding against the defendant, the jury determined that the defendant had engaged in exclusionary conduct in May and September 1994, but also found that the plaintiff first showed an intent and preparedness to enter the market in December 1994. *Id*. at 711. The defendant moved for judgment notwithstanding the verdict on the ground that the plaintiff had failed to prove antitrust injury because the jury's findings established that the exclusionary conduct took place before plaintiff was a competitor or potential competitor in the relevant market. The lower court denied the motion, stating that the conduct could have had "continuing effects" on plaintiff "so as to cause antitrust injury." *Id.* at 712.

The Ninth Circuit reversed because "[o]nly an actual competitor or one ready to be a competitor can suffer antitrust injury," and plaintiff was neither. *Id.* at 711. Rather, the court explained, the plaintiff was a "bystander who was pawing at the ground" that had "failed every test of preparedness to be a [competitor in the relevant market] prior to December 1, 1994," and thus,

the defendant's conduct in May 1994, could not "constitute antitrust injury." *Id.* at 712. A "nascent business," the court reasoned, simply "does not possess the property to which antitrust injury can be done." *Id.* at 712 (*citing* Areeda & Hovenkamp, *Antitrust Law*). The Ninth Circuit further rejected the lower court's concept of "continuing effects," and succinctly summarized: "Suffering no antitrust injury before the December date because it was unprepared, and suffering no antitrust injury after the December date because no [alleged anticompetitive conduct took place], [plaintiff] has no antitrust case." *Id.*

Under the foregoing standard, Spring comes no closer to pleading an "intention and preparedness" to sell a generic version of Thiola in its Amended Complaint than it did in its original complaint. Indeed, as discussed below, Spring still fails to plead "every test of preparedness." *Id.*

1. Spring Fails to Allege It Has Background and Experience

Spring still makes *no* allegations about its "background and experience" (Order 35), let alone anything regarding developing or marketing pharmaceutical products—generic or otherwise. Indeed, it admits that a generic version of Thiola would be its "first product." (Am. Compl. ¶ 71); *cf Roxane*, 2010 WL 331704 at *4 (noting plaintiff had "over 20 years of experience marketing generic drugs in the United States."). Nor does it allege that it has any personnel with relevant experience. To the contrary, the only employee the Amended Complaint identifies as affiliated with Spring is Charles Li, its "CEO" and "sole member," who is an antitrust lawyer. In sum, as this Court stated, Spring is "clearly unlike the Roxane plaintiff." (Order 40).

2. Spring Fails to Allege It Has The Financial Ability to Enter the Market

Spring pleads no new facts establishing that it had the "financial ability to enter the market." (Order 35). Rather, it merely re-pleads what it pled before in conclusory fashion: that it has "secured financing sufficient to cover" the costs to "develop the product and secure regulatory approval" and to "bring[] a generic tiopronin product to market." (Am. Compl. ¶ 90). As before,

Spring points to three sources: Charles Li's personal investments, "operational funding," and a document from an entity in China. (*Id.*).

As before, Spring does not allege the amount of "personal investments" and "operational funding" that it receives. *(Id.)* Nor does it allege the source of its alleged "operational" funding, and with respect to the document from the China-based entity, it is merely a "letter of intent" that plainly states on its face that it "**does not represent an enforceable legal contract**," and that after Spring received the samples, the entity would perform a due diligence review before deciding whether to invest. (Am. Compl. Ex. K) (emphasis added). Notably, although Spring has now been in possession of samples for six months, it does not allege that the entity from which it received the letter of intent has in fact conducted due diligence, much less that it has provided any funding.

In sum, any alleged funding is either of some undisclosed amount or "subject to numerous future conditions" and "in the abstract." Spring has thus failed to allege that it has the "financial ability to enter the market." (Order 35). *See Cavanaugh v. Cascor, Inc.*, 1996 WL 283676 at * 3 n.5 (E.D. Pa. 1996) (finding plaintiff lacked standing, in part, because it had "not demonstrated that he had the financial ability to enter the market" and because entry was "subject to numerous future conditions.") (citing Areeda & Hovenkamp, *Antitrust Law* § 374); *see also Hayes v. Soloman*, 597 F. 2d 958, 975 (5th Cir. 1979) ("The mere possibility of financing being available in the abstract is not enough. Showing that someone somehow could possibly obtain financing is not the same as showing that plaintiffs themselves were able and prepared to do so."); *Roxane*, 2010 WL 331704 at *3; *Brotech*, 2004 WL 1427136 at *5.

3. Spring Fails to Allege It Has Taken Affirmative Actions to Enter the Market

"Most importantly," Spring has failed to plead any new facts to demonstrate that it had taken "affirmative actions" to enter the market at the time of the allegedly unlawful conduct. (Order

35). It relies on the same "attempts to obtain Thiola," "discussions," "negotiations," and agreements that this Court found to be insufficient the first time around. (Order 39-40; Am. Compl. ¶¶ 81-83). Specifically, this Court found that these allegations were insufficient to confer antitrust standing, in part, because Spring failed to explain how they demonstrated a sufficient "manufacturing and distribution" network. (Order 40 (*citing Roxane*, 2010 WL 331704 at *4)).

Spring still does not explain how the two vendors it identifies are sufficient to bring a generic drug product to market and to the contrary, Spring readily admits that there are many other agreements it will need to put in place in order to enter the market with a generic version of Thiola, but fails to allege that it has even "started the process" of entering those contracts. For example, it states:

- Spring "*intends* to source the tiopronin. . .from MSN Life Sciences Private Ltd.";
- "*Once* the generic tiopronin product is developed. . .Spring *will need to* conduct bioequivalence testing";
- "If the generic tiopronin product is not eligible for a biowaiver, Spring *will engage* an additional third-party contractor to perform any additional required testing";[16]
- "Spring *intends* to contact with a distributor to provide the generic tiopronin product to wholesalers and pharmacists once it has secured FDA approval";
- "Spring *intends to* use Prinston's subsidiary Solco Healthcare, or a similar entity, to market and distribute its generic tiopronin. Spring *will enter* into the necessary contracts with a marketer or distributor at the appropriate stage of product development."

(Am. Compl. ¶¶ 84-87, 91-92) (emphasis added). Indeed, Spring fails to even allege that it has a contract in place to conduct bioequivalence testing—the very testing for which it claims it needed the samples. (Am. Compl. ¶ 85). Therefore, by Spring's own admissions, and just as this Court

[16] Spring further states that it has been advised, by some unknown entity, that there are many "capable contractors" that "will be available for contracting at the appropriate stage of product development." (Am. Compl. ¶ 86 and n. 63). This, of course, means that Spring has taken no steps to identify or communicate with such a contractor.

found before, Spring's alleged existing relationships fall short of a sufficient "manufacturing and distribution" network and do not demonstrate an intent and preparedness to enter the market.

As established above, Spring's alleged actions *after* it received samples cannot be used to demonstrate antitrust standing. *See Roxane*, 2010 WL 331704 at *3; *Bourns*, 331 F. 3d at 711. In any event, if anything, Spring's conduct after receiving samples confirms that it never had the intention or preparedness to enter the market. If Spring had genuinely intended to enter the market, one would expect that upon obtaining the samples it claimed it needed, Spring would have immediately taken steps to enter the market. But in fact, after receiving the samples in October 2019, Spring apparently did nothing. It was not until two months later, after the Court granted Defendants' motion to dismiss with leave to amend, that Spring alleges it did anything. (Am. Compl. ¶ 84). Even then, the most Spring can say is that it has now "identified" the "ingredients" that will be used in the product (information that is readily available on the internet[17]), "outlined relevant analytical methods," and "developed a detailed timeline." (*Id.*).[18]

Notably, the "detailed" development timeline from Spring's CDMO—on which Spring heavily relies in its attempt to allege sufficient preparedness—identifies more than twenty development activities that were supposed to take place between the "kickoff meeting" in December and mid-February, none of which Spring alleges it or its vendor have conducted. (Am. Compl. Ex. G).[19] Indeed, most of these steps are predicated on Spring providing its CDMO with the Active

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[17] *See supra* n. 14.

[18] The CDMO's "detailed timeline" is little more than a reiteration of drug development steps and procedures set forth in the CDMO's proposal and contract. (Compare Am. Compl. Ex. A with Am. Compl. Ex. G).

[19] This suggests that Spring will not meet its estimated or alleged market entry date listed in its CDMO's "detailed" timeline.

Pharmaceutical Ingredient ("API") for the drug, but Spring admits that it has not even entered into a contract to purchase API. (Am. Compl. ¶ 84).[20] Spring's failure to take steps to enter the market even after it obtained samples further establishes that Spring is not a genuine plaintiff that intended to enter the market but an opportunistic one hoping to extract treble damages.

In the words of this Court, "the definition of sufficient affirmative steps is not precise," but Spring "is clearly unlike the Roxane . . . plaintiff." (Order 40). Spring has not pled a single new allegation that changes that conclusion.

Spring has had ample opportunity, yet still fails to plausibly allege that it has antitrust standing. That is because there are no facts it can plead to support its allegations. Any further amendment would be futile and this Court should use its discretion to dismiss Spring's Amended Complaint with prejudice. *See, e.g.*, *Williams v. Phila. Hous. Auth.*, 826 F. Supp. 952, 953 (E.D. Pa. 1993) (J. Joyner) ("The court may deny leave to amend, among other reasons, on the basis of the futility of the amendment."); *Joey's Auto Repair & Body Shop v. Fayette Cty.*, 785 F. App'x 46, 51 (3d Cir. 2019) ("Because Plaintiffs' second amended complaint was a futile attempt to correct issues with their first amended complaint, we will affirm the District Court's denial of leave to amend.").

[20] The timeline makes clear that Spring was expected to provide the CDMO with the API (tiopronin) by December 25, 2019 (Am. Compl. Ex. G), which Spring has admitted that it has not done (Am. Compl. ¶ 84) ("Spring intends to source the tiopronin—referred to as the "active pharmaceutical ingredient" or "API"—from MSN Life Sciences Private Ltd."). A CDMO cannot "develop a tiopronin product," let alone one that "is bioequivalent to Thiola" and a generic tiopronin product is not "an imminent reality" if Spring has not purchased, or even entered into a contract to purchase, tiopronin. *Id.* Because it has not yet even purchased the API, Spring admits its developed product won't be completed until, at the earliest, September 2020. *Id.* Spring did not need the samples to purchase the API, or develop its product, but in any event, it received the samples in October 2019 and it offers no excuse for its delays.

B. Spring Has Not Pled a Monopolization or Attempted Monopolization Claim.

Even if Spring could show that it has antitrust standing to pursue its claims, Spring's claims would still fail because the Complaint does not allege a cognizable theory of antitrust liability under Section 2 of the Sherman Act. In order to make out its monopolization claims, Spring must show: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). Simple possession of monopoly power is not enough; a defendant must also engage in exclusionary conduct to violate Section 2. *See* Areeda & Hovenkamp, *Antitrust Law* ¶ 650a(1). "The [Sherman Act] directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself." *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993)).[21]

1. Retrophin Has No Duty Under the Antitrust Laws to Aid Its Rivals.

The Supreme Court holds up the Sherman Act as the "the Magna Carta of free enterprise." *Verizon Commc'ns v. Law Offices of Curtis v. Trinko*, 540 U.S. 398, 415 (2004). Accordingly, it has established that no company, *not even a monopolist*, has a duty to aid its rivals because such a duty would be in "tension with the underlying purpose of antitrust law." *Id.* at 407-408; *see also United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919) (The antitrust laws respect and protect

[21] Spring cursorily adds an attempted monopolization claim without any additional allegations. To prevail on an attempted monopolization claim under § 2 of the Sherman Act, "a plaintiff must prove that the defendant (1) engaged in predatory or anticompetitive conduct with (2) specific intent to monopolize and with (3) a dangerous probability of achieving monopoly power." *See Queen City Pizza v. Domino's Pizza*, 124 F.3d 430, 442 (3d Cir. 1997). This claim fails for the same reasons its monopolization claims fail.

the right of a "manufacturer . . . freely to exercise his own independent discretion as to parties with whom he will deal."); *Mannington Mills, Inc. v. Congoleum Indus., Inc*., 610 F.2d 1059, 1069 (3d Cir. 1979) ("We seriously doubt that an arbitrary or discriminatory unilateral refusal to deal by a lawful monopolist is actionable . . . ."); *Only v. Ascent Media Grp., LLC*, 2006 WL 2865492 at *4 (D.N.J. 2006) ("There is no general duty to deal, and a company's refusal to do business with a potential business partner ordinarily does not give rise to a claim for relief under Section Two of the Sherman Act," other than in "exceptional circumstances."); *Goldwasser v. Ameritech Corp*., 222 F.3d 390, 400 (7th Cir. 2000) ("[A] complaint . . . which takes the form 'X is a monopolist, [and] X didn't help its competitors enter the market so that they could challenge its monopoly . . .' does not state a claim under Section 2. The reason is because the antitrust laws do not impose that kind of affirmative duty. . . .").

Thus, only in narrow circumstances can a monopolist's refusal to cooperate with rivals violate Section 2, and the courts have "been *very* cautious in recognizing such exceptions." *Trinko*, 540 U.S. at 408 (emphasis added). This is because the compelled sharing of resources: (1) "lessen[s] the incentive . . . to invest" in those resources; (2) "requires [federal courts] to act as central planners" despite them being "ill suited" to assume this role; and (3) "may facilitate the supreme evil of antitrust: collusion."[22] *Id.* at 407-08; *see also Novell, Inc. v. Microsoft Corp.*,

[22] Moreover, courts should be wary of expanding Section 2 liability to cover the conduct alleged in the Amended Complaint given the enactment of The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 ("CREATES" or the "Act") on December 19, 2020, which provides a private right of action for prospective generic entrants who claim that they are denied timely access to samples of the product they need for regulatory testing by pioneer drug pharmaceutical companies. H.R. 1865, 116th Cong. § 610 (2020). Successful plaintiffs are entitled to injunctive relief as well as reasonable attorney's fees and related legal costs, and companies that fail to comply are exposed to significant penalties, including disgorgement of profits. *Id.* As discussed extensively in *Trinko*, the existence of a regulatory structure designed to deter and remedy the exact harm that Spring alleges, weighs against creating a new, amorphous exception to the traditional antitrust principle that competitors have no duty to

731 F.3d 1064, 1076 (10th Cir. 2003) ("If the [refusal to deal] doctrine fails to capture every nuance, if it must err still to some slight degree, perhaps it is better that it should err on the side of firm independence—given its demonstrated value to the competitive process and consumer welfare—than on the other side where we face the risk of inducing collusion and inviting judicial central planning.").

The Supreme Court found an exception to its general rule in *Aspen Skiing v. Aspen Highlands Skiing*, 472 U.S. 585 (1985), but subsequently distinguished the case as a "limited exception" that lay "at or near the outer boundary of § 2 liability." *Trinko*, 540 U.S. at 409. In *Aspen Skiing* the defendant chose to end a long-standing partnership with a competitor to offer bundled ski lift tickets to both companies' mountains. 472 U.S. at 585. The court found that the defendant's termination of a prior course of voluntary dealing suggested a willingness to "forego . . . short-run benefits" in order to "reduc[e] competition . . . . over the long run by harming its smaller competitor." *Id.* at 608.

Spring tries to fit within the *Aspen Skiing* exception, alleging that Defendants "sacrifice[ed] short-term profits to achieve anticompetitive ends." (Am. Compl. ¶ 65; *see also* ¶ 126). If the sacrifice of short-term profits were sufficient to allege an antitrust violation, the

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deal with their rivals. 540 U.S. at 414; *see also e.g.*, *S. Judiciary Comm., 114th Cong.* (Jun. 21, 2016) (opening statement of Sen. Mike Lee (R-UT)) ("While some parties have attempted to use the antitrust laws to address this conduct . . . the answer is not to pile antitrust enforcement on top of regulation, but to fix the underlying problem: the law itself. I believe the CREATES Act does just that."); *Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, at 7 (Jul. 16, 2018) (advocating for "a legislative solution" given that legislation could "avoid the uncertainty of litigation and, unlike a lengthy antitrust case, provide an immediate solution to this challenging problem"). That is because, as the Supreme Court counseled, in regulated industries, "judicial oversight under the Sherman Act would seem destined to distort investment and lead to a new layer of interminable litigation." *Trinko*, 540 U.S. at 414.

Aspen Skiing exception would swallow the general rule that competitors need not aid their rivals. *Novell, Inc.*, 731 F.3d at 1075 ("Of course, firms routinely sacrifice short-term profits for lots of legitimate reasons that enhance consumer welfare."). Something more is required, such as that the defendant's foregoing short-term profits was economically irrational to the point that it reveals a "distinctly anticompetitive bent." *Trinko*, 540 U.S. at 409.

Spring does not do so here, alleging only that, Retrophin did not respond to a request from an unknown entity to purchase a small quantity of "samples" of Thiola. (*See* Am. Compl. ¶¶ 65, 75-80). Retrophin is in the business of selling Thiola to patients who need it and has an established distribution system to do so effectively. Its failure to respond to a random request to sell a *de minimis* amount of product to an unknown entity comes nowhere close to the sort of economically irrational behavior that the Supreme Court found to evidence anticompetitive intent in *Aspen Skiing*, where the defendant terminated a long-standing and profitable relationship. *See, e.g.*, *3Shape Trios A/S v. Align Tech., Inc.*, 2019 U.S. Dist. LEXIS 137982, at *15 (D. Del. 2019) (Plaintiff's "allegations about [defendant's] unaccepted proposals do not suggest a plausible harm to competition, nor has [plaintiff] explained how an unaccepted offer to enter into a business arrangement could have resulted in any harm to competition.").

Spring's allegations concerning Retrophin's introduction of Thiola EC also do not support its allegation that Retrophin's refusal to provide samples was driven by anticompetitive intent. (Am. Compl. ¶ 67). The law is clear that "simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct." *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014). That is because investing into introducing new products, without withdrawing the older product, "adds choices," and therefore benefits consumers. *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 148-49

(D.D.C. 2008); *see also In Re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 269 (D. Mass. 2017) (dismissing plaintiff's product hopping claims with respect to the "soft switch" because "soft switches do not have the same anticompetitive result [as hard switches] because 'the market can determine whether one product is superior to another . . . 'so long as the free choice of consumers is preserved.'").[23] In addition, Spring points to no conduct by Retrophin to "persuade" consumers to use Thiola EC, over Thiola IR, other than the use of a "pop-up" advertisement. (Am. Compl. ¶ 67). Simple advertising is not enough to evidence any sort of anticompetitive conduct. *In re Suboxone Antitrust Litig*., 64 F. Supp. 3d at 682; *Walgreen Co.*, 534 F. Supp. 2d at 152 ("Plaintiffs have not identified any antitrust law that prohibits market switching through sales persuasion short of false representations or fraud"); *see also New York ex. rel. Schneiderman v. Activis PLC*, 787 F.3d 638, 654 (2d Cir. 2015) ("*Namenda*") ("As long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.").

To be sure, courts have found antitrust liability in situations where companies have introduced a new product while also removing an older formulation of the same product, which is typically known as a "hard switch." *See, e.g.*, *id.* at 653-54 ("Certainly, neither product withdrawal nor product improvement alone is anticompetitive . . . [a monopolist's actions are anticompetitive only] when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits . . .

[23] Spring's Amended Complaint is not clear as to whether it is contending that Retrophin's introduction of Thiola EC, separate from Retrophin's alleged refusal to deal Thiola IR, is anticompetitive. To the extent it is making such a claim, its claims fail because introducing a new product and adding choices for customers is competition enhancing and lawful. *In re Suboxone Antitrust Litig*., 64 F.Supp.3d at 682.

Defendant's hard switch crosses the line from persuasion to coercion and is anticompetitive."). Spring concedes that this is not the situation here, (Am. Compl. ¶ 67), as Thiola IR remains on the market, and therefore cannot explain how Retrophin's lawful introduction of a new product can evidence anticompetitive intent.

Spring's claims also fail because it does not even allege it was foreclosed from obtaining samples from sources other than Defendants. Rather, Spring merely states that it was "*practicably* unable to procure the[] samples from an alternative source." (Am. Compl. ¶ 123 (emphasis added), ¶ 77. This is a plain concession that there are other sources of Thiola available to Spring.

In addition, Spring had other ways of competing; it could, for example, have developed a tiopronin formulation under an NDA, a process that does not involve demonstrating bioequivalence and therefore does not require samples of the branded drug.

If Spring could have obtained samples from other sources, or come to market in some other way without Defendants' aid, then Defendants' alleged refusal is not exclusionary conduct that denied Spring access to the market and Spring has failed to state a claim. *See Natco Pharma Ltd. v. Gilead Sciences, Inc.*, 2015 WL 5718398, at *4 (D. Minn. 2015) (granting defendant's motion to dismiss because "a refusal to deal claim requires showing that the requested assets are completely unavailable."); *see also* Areeda & Hovenkamp, *Antitrust Law* ¶ 772d3 (2d ed. 2008) ("The doctrine must be strictly limited to circumstances where the requested assets are completely unavailable.").

In sum, the antitrust laws do not confer a duty to deal with rivals. That is especially true here, where the "rival" is an entity that is not even in the market and has not adequately alleged that it can come to market. Any refusal to deal with such an entity can have no impact on

competition.

2. Thiola Is Not an Essential Facility.

Nor can Spring claim that Thiola samples are an "essential facility" that Retrophin must provide because Spring cannot enter the market without them. (*See, e.g.*, Am. Compl. ¶¶ 121-122, 125-130). Indeed, the Supreme Court has *never* recognized the "essential facilities" doctrine and expressly labeled it a "limited exception" "crafted by some lower courts." *Trinko*, 540 U.S. at 409-11 (citing Phillip E. Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 Antitrust L.J. 841 (1989)).

Since then, lower courts and commenters alike have questioned the vitality and prudence of the doctrine and this Court has recognized that the doctrine applies only in the "most extreme cases." *Pocono Invitational Sports Camp v. Nat'l Collegiate Athletic Ass'n*, 317 F. Supp. 2d 569, 587 n.23 (E.D. Pa. 2004); *see also* Areeda & Hovenkamp, *Antitrust Law* ¶ 771c ("[W]e state our belief that the essential facility doctrine is both harmful and unnecessary and should be abandoned.").

Fundamentally, the doctrine cannot apply if the denied facility is not *essential* because there are other means of competing. *Id.* ¶ 736.2b (Supp. 1986) ("[A] facility is not essential if plaintiff can effectively compete without it."); Herbert Hovenkamp, *Unilateral Refusals to Deal, Vertical Integration, and the Essential Facility Doctrine* (Univ. of Penn Law Legal Scholarship Repository, Jul. 2008) at 35 ("A rule that permits firms to obtain from a larger rival inputs that they or other rivals could possibly construct for themselves reduces rather than increases competitive incentives."); *Cyber Promotions, Inc. v. Am.Online, Inc.*, 948 F. Supp. 456, 464 (E.D. Pa. 1996) (finding defendant had not established essential facilities doctrine because it "has not shown any reason why it could not (other than perhaps because it would have to pay

its own way) use its own servers to create its own commercial online internet service or advertising website.").

Here, not only does Spring allege there were other sources from which it may have been able to receive the samples (*supra* p. 23), Spring does not allege that it had no other routes to market. Indeed, Spring had another path to entry because a potential generic competitor can attempt to bring a competing product to market by filing a NDA rather than using the short-cut approach under the ANDA process, as discussed above. (*Supra* p. 23). This may be more burdensome than filing an ANDA, but the most economical route is not an essential facility when other routes are available. *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 450 (2009) (A monopolist "certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous."); *Trinko,* 540 U.S. at 407-08, 415-16 ("The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition"; "Firms may acquire monopoly power by establishing an infrastructure that renders them uniquely suited to serve their customers. Compelling such firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law. . . ."); *see also Midw. Gas Servs., Inc. v. Ind. Gas. Co*., 317 F.3d 703, 714 (7th Cir. 2003). As the court in *Goldwasser* explained, duplicating an incumbent's facilities may require a large investment, take substantial time, and require a lot of effort, but that does not mean the incumbent's facilities are "essential." 222 F. 3d at 399.

C. Plaintiff Has Not Alleged a Conspiracy to Monopolize or to Restrain Trade.

A plaintiff asserting a Section 1 claim must adequately plead: "(1) an agreement (2) to restrain trade unreasonably." *Lifewatch Services Inc. v. Highmark Inc.*, 902 F.3d 323, 331 (3d Cir. 2018). In order to succeed on a conspiracy to monopolize theory brought under § 2 of the Sherman Act, a plaintiff must prove: "(1) an agreement to monopolize; (2) an overt act in furtherance of the

conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged." *Howard Hess Dental Labs. Inc. v. Dentsply Int'l*, 602 F.3d 237, 253 (3d Cir. 2010). Therefore, to prevail on a conspiracy claim under Section 1 *or* Section 2, a plaintiff must first establish an agreement, *i.e.*, that the defendants had "a unity of purpose or a common design and understanding or a meeting of the minds in an unlawful arrangement," *id.* at 254, or a "conscious commitment to a common scheme designed to achieve an unlawful objective," *Friedman v. Del. Cty. Mem'l Hosp.*, 672 F. Supp. 171, 196 (E.D. Pa. 1987).[24] Here, Spring has failed to adequately plead "concerted action" to preclude generic competition, and the Court need not analyze any other factors in order to dismiss Spring's claims. However, even if Spring had pled a conspiracy amongst Defendants, Spring has also failed to plead that the alleged conspiracies were unlawful restraints of trade, that Defendants took steps in furtherance of the conspiracy, or that Defendants acted with specific intent. Thus, Spring's conspiracy claims fail.

1. The "Exclusive" Agreements Do Not Demonstrate Concerted Action to Restrain Trade Under the Antitrust Laws.

Spring appears to claim that Mission, Alamo, Eversana, and Retrophin violated Sections 1 and 2 of the Sherman Act by "conspiring" to preclude generic competition by limiting access to Thiola. (*See, e.g.*, Am. Compl. ¶¶ 55, 134, 154). However, Spring's only allegations of "concerted action" are two presumptively lawful contracts: a licensing contract between Retrophin and Mission and a distribution contract between Retrophin and Eversana. *Id.* at ¶ 155. Neither of these agreements demonstrates a "meeting of the minds in an *unlawful arrangement*," *Dentsply*, 602 F.3d at 254 (emphasis added), *or* a "conscious commitment to a common scheme designed to achieve an *unlawful objective*," *Friedman v. Del. Cty. Mem'l Hosp.*, 672 F. Supp. at 196 (emphasis

[24] Under antitrust jurisprudence, the terms conspiracy, agreement, and concerted action are used interchangeably. *Lifewatch Services Inc.*, 902 F.3d at 332; *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 99 (3d Cir. 2010).

added), as required by law.

"The Third Circuit has held that there is no antitrust agreement under § 1 'when a party has simply entered into a permissible contract with the defendant or when the defendant has enforced a contractual right with another party.'" *Mylan Pharm. v. Celgene Corp.*, 2014 WL 12810322, at *8 (D. Del. 2014) (citing *Harold Friedman, Inc. v. Kroger Co*., 581 F.2d 1068, 1078 (3d Cir. 1978), *abrogated on other grounds by Ideal Dairy Farms, Inc. v. John Labatt, Ltd*., 90 F.3d 737 (3d Cir. 1996). Rather, Spring must plead a "conscious commitment" to a refusal to deal with Spring "separate and apart from the fact of entering into the facially neutral contract[s]." *Gulf States Reorganization Grp., Inc. v. Nucor Corp.*, 822 F. Supp. 2d 1201, 1221 (N.D. Ala. 2011) (proof of a conscious commitment "required some showing of [defendant's] objective, separate and apart from the fact of entering into the facially neutral contract with [primary defendant]"); *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 212 (3d Cir. 1992) ("[T]he emphasis is upon the participant's '*commitment to [the] scheme* [which is] designed to achieve an unlawful purpose' which is crucial.").

Merely alleging the existence of the licensing and distribution agreements is "insufficient to obviate the need for some proof of an objective to restrain trade . . .." *Gulf States*, 822 F. Supp. 2d at 1221 (Plaintiff makes the "astounding argument that the written contract…is itself direct evidence of concerted conduct causing anticompetitive harm . . .. The correct interpretation is that the *joint meeting of the minds must incorporate the illegal restraint and, thus, those elements are inextricably intertwined.*") (emphasis added); *See also id.* at 1222 n.24, 1224 ("[T]he only joint action agreed to . . . was an ordinary commercial brokerage agreement."); *Toscano v. PGA*, 258 F.3d 978, 984 (9th Cir. 2002) ("[T]he local sponsors' contracts demonstrated only that they agreed to purchase a product. . . They did not commit to a common scheme to act in restraint of trade. . .

. the local sponsors accepted the fact that the tournaments would be operated according to the PGA Tour's rules and regulations, not that they agreed to use those rules to restrain trade.").

In *Mylan*, the plaintiff argued and lost on the same conspiracy arguments that Spring presents, alleging that the defendants engaged in an unlawful conspiracy by entering into "exclusive distribution" agreements that prevented the plaintiff from accessing the branded samples it required for FDA approval of its ANDA. 2014 WL 12810322 at *5. The court dismissed these claims, finding that it is not "enough to simply plead that a contract exists" in order to show a "conscious commitment" to an anticompetitive scheme and that plaintiff appeared to "conflate evidence of a contract with evidence of an unlawful 'agreement' to restrain trade under § 1." *Id.* at *8. In so stating, the court explicitly rejected the argument that "direct evidence" of any agreement is sufficient to satisfy conspiracy claims under the Sherman Act; there must be something more. *Id.*

Likewise, here, Spring merely pleads that certain contracts exist and that direct evidence of those agreements satisfies the conspiracy requirement of the Sherman Act. Indeed, with respect to Mission and Alamo, it offers unremarkable statements such as, "Alamo . . . is . . . Mission's contract sales force business. . . a key piece of Retrophin's revenue-growth strategy" and "Mission . . . is 'Retrophin's great partner.'" (Am. Compl. ¶ 52). As to Eversana, it claims the company serves as Retrophin's "exclusive distributor" of Thiola. (*Id*. at ¶ 55). None of this demonstrates a "meeting of the minds" in an unlawful scheme to refuse to provide samples to generic companies. *Dentsply*, 602 F.3d at 254.

Even if Spring had properly alleged that *Retrophin* had an objective to restrain trade or monopolize (it has not), that would not be sufficient under the Sherman Act's conspiracy requirements. Spring must allege that *each supposed conspirator* joined a common scheme to

restrain trade or monopolize. Any unilateral exploitation of an "otherwise routine business arrangement" with Mission, Alamo, and Eversana to implement an anticompetitive scheme "simply does not transform that ordinary business arrangement into antitrust conspiracy." *Gulf States*, 822 F. Supp. 2d at 1221 n.21, 1225; *see also Mylan*, 2014 WL 12810322 at *8 ("Nowhere does [plaintiff] plead that [defendant's] distributors. . . shared its purpose. . . or that they had a common anticompetitive goal."); Areeda & Hovenkamp, *Antitrust Law* ¶ 1474(c) ("[V]ertical agreements are ubiquitous and essential to distribution . . . in vertical cases involving distribution restraints . . . the question must be whether the *right kind* of agreement exists."). Here, Plaintiff has not alleged that Defendants Mission, Alamo, or Eversana are anything but entities that entered into standard licensing and distribution agreements.

Further, while the contracts may have specifications pursuant to which Retrophin will pay royalties to Mission for sales of Thiola, and Eversana will distribute Thiola, Spring does not allege that the agreements contain any sort of blanket restriction on Retrophin's provision of Thiola to generics. That is, Plaintiff did not allege that the contracts bind Retrophin in any way—Retrophin can still provide the samples under the terms of the contracts (as it, in fact, has)—and therefore, they cannot be a "meeting of the minds" of all the Defendants to restrict access to Thiola.

In addition, Spring admits that Retrophin unilaterally imposed its specialty distribution system, which is at the core of its concerns. (Am. Compl. ¶ 8 ("Retrophin. . . removed the product from pharmacy shelves and moved Thiola into a closed distribution system"), ¶ 53 ("Retrophin moved the drug into a closed distribution system."). All of this demonstrates that there is no meeting of the minds amongst Defendants. Moreover, to the extent Spring is alleging that specialty pharmacy models are anticompetitive on their face, its arguments fail because Spring has not alleged that such models are without procompetitive benefits.

Other than these two contracts, Spring does not allege a single fact to suggest that the Defendants conspired to refuse to deal with Spring. Rather Spring appears to insinuate that Mission, Alamo, and Eversana's "conscious commitment" to Retrophin's alleged unlawful scheme can be inferred because they entered and stood to profit from the licensing and distribution agreements. (Am. Compl. ¶ 51 ("The Agreement also required Retrophin to appoint Alamo . . . providing Mission an additional form of compensation under the exclusive deal."), ¶ 63 ("Mission, for its part, continues to manufacture and supply Thiola exclusively to Retrophin" in exchange for a cut of Retrophin's product sales, "a direct financial benefit from its participation in this anticompetitive distribution scheme."), ¶ 13 ("Retrophin, Mission, Alamo, and Eversana continued to use—and profit from—the exclusive licensing agreement and restricted distribution scheme designed to prevent generic competition.")).

This, too, fails. Receiving a licensing royalty and commission pursuant to an ordinary business arrangement is insufficient to infer a conscious commitment to an unlawful scheme. *Gulf States*, 822 F. Supp. 2d at 1225 ("Moreover, the mere fact that [defendant] entered into an agreement to perform its usual business, even if it was a higher profit than usual, does not show that it conspired to do anything other than make money. [Plaintiff] argues that the profit margin . . . [indicates] . . . ulterior motives. . . but that is not enough and there is no evidence that [they] entered into the agreement with a shared objective to achieve those alleged unlawful ends."); *Dentsply*, 602 F.3d at 256 ("Plaintiffs tell us, the Dealers would all benefit from Dentsply's policies because they would be able to charge . . . inflated prices. . . but simply because each Dealer on its own might have been economically motivated to exert efforts to keep Dentsply's business and charge the elevated prices Dentsply imposed does not give rise to a plausible inference of an agreement among the Dealers themselves"); Areeda & Hovenkamp, *Antitrust Law* ¶ 1474(a), (c)

("The broker who merely earns its commission or the distributor taking its usual markup does not share a conscious commitment to a common scheme designed to achieve an unlawful objective.").

2. The Alleged Agreements Are Not Unreasonable Restraints of Trade.

Retrophin's "exclusive agreements" cannot be considered "conspiracies" under the Sherman Act, but even if they could, Spring has not plausibly alleged that they "restrain trade unreasonably." *Lifewatch Services Inc.*, 902 F.3d at 331. In fact, Spring has not even alleged which provisions in these contracts supposedly prohibit Defendants from providing samples to Spring. To be sure, all contracts have restraints, including licensing or distribution contracts, and the question for the Court is whether Spring has sufficiently pled that those provisions are unreasonable. *Bd. Of Trade Of The City of Chi. v. United States*, 246 U.S. 231, 238 (1918) ("Every agreement concerning trade, every regulation of trade, restrains. To bind, to restrain, is of their very essence. The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.").

Here, Spring cannot plead that these "exclusive agreements" are unreasonable because under the antitrust laws, these vertical agreements (*i.e.*, between entities at different levels of a distribution chain and not between horizontal competitors) are "presumptively legal." *Elecs. Commc'ns Corp. v. Toshiba Am. Consumer Prods.*, 129 F.3d 240, 245 (2d Cir. 1997) ("[T]he allegations in [Plaintiff's] complaint establish nothing more than a run-of the-mill exclusive distributorship controversy. . . Such exclusive distributorship arrangements are presumptively legal."); *Yagoozon, Inc. v. Kids Fly Safe*, 2014 U.S. Dist. LEXIS 92283 at *23-24 (D.R.I. 2014) ("[N]on-price vertical restraints, including those that amount to a true exclusive distributorship, not only are the most benign in the antitrust panoply, but are generally procompetitive and should not be deterred by antitrust enforcement."); *see also* Areeda & Hovenkamp, *Antitrust Law*

¶ 1474(c) ("[V]ertical agreements are ubiquitous and essential to distribution . . . in vertical cases involving distribution restraints . . . the question must be whether the *right kind* of agreement exists.").

That is, courts have found any restraint in such licensing and distribution agreements presumptively reasonable because they are ancillary to a broader purpose that promotes competition. *Id.*[25] As the *Mylan* court noted, "contractual restraints fall within the prohibition of Section 1 only when their purpose and effect is found to have imposed an undue restraint on commerce" not where "[the] restraint of trade appears to be collateral to the main purpose of the contracts which is to distribute [the products]." *Mylan*, 2014 WL 12810322 at *8.

Thus, Spring's assertion that the "exclusive" agreements explicit objective was to "thwart[] generic competition" is unfounded in allegation or law. (Am. Compl. ¶ 7-8; *see also* ¶ 9 ("The clear purpose and effect of Defendants' agreement was to unduly restrain trade.")). "It is an axiom of antitrust law, however, that merely saying so does not make it so for pleading sufficiency purposes." *Dentsply*, 602 F.3d at 258.[26]

3. Spring Fails to Allege Steps in Furtherance of the Conspiracy or Defendants' Specific Intent.

In order for a Section 2 conspiracy claim to survive a motion to dismiss, a plaintiff must

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[25] Antitrust law recognizes that these types of vertical arrangements (*i.e.,* exclusive distribution agreements) typically benefit competition by encouraging investment in promotion and in providing high quality services to customers. Indeed, this potential for significant procompetitive benefits is why, as reported by the leading antitrust treatise, no court in the last 25 years has "found territorial and customer restrictions" in vertical distribution agreements to be "unreasonable." American Bar Association: Antitrust Law Developments at 156-57 (7th ed. 2012).

[26] Spring further appears to insinuate that the contracts are unlawful "because Mission expressly agreed that it would not sell, distribute, and supply its own generic version of [Thiola] unless another first entered the market." (Am. Compl. ¶ 9). Such a term does not evidence a refusal to deal. On its face, the provision contemplates that generic entrants may enter the market.

plead sufficient facts to show that defendants took "overt acts" in furtherance of the alleged conspiracy. *Dentsply*, 602 F.3d at 253. Here, Spring states that "[e]ach Defendant also took overt acts in furtherance of this conspiracy," but identifies no facts to support such a conclusory statement. (Am. Compl. ¶ 135). It is not sufficient for pleading purposes to simply recite elements of a claim. *Twombly*, 550 U.S. at 555 ("[E]ntitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" (internal quotation marks, alteration, and citation omitted)).

In much the same way, Spring states, with no support, that the Defendants "entered into exclusive agreements with the specific intent to monopolize." (Am. Compl. ¶ 134). These allegations fail for the same reason its conscious commitment allegations fail: at most, Spring's allegations show that Mission, Eversana, and Alamo had the specific intent to enter into licensing and distribution agreements, they do not show that Defendants had a specific intent to engage in an unlawful plan to monopolize the market by refusing to provide samples.[27] *Futurevision Cable Sys.*, 789 F. Supp. at 773 (S.D. Miss. 1992) ("For the same reasons that [plaintiff] has failed to state a claim that [the defendants] unlawfully conspired to restrain trade under section 1 of the Sherman Act, the court finds that [plaintiff] has failed to state a claim that [the defendants] unlawfully conspired to monopolize under section 2 of the Act.").

As this Circuit has articulated:

[T]he only actual conduct the Plaintiffs have alleged on the part of the [ancillary

[27] In fact, courts have noted that "a conspiracy to monopolize in violation of section 2 requires even greater proof than is necessary to prove an unreasonable restraint of trade under section 1," *i.e*. a conscious commitment to an unlawful scheme. *Futurevision Cable Sys. of Wiggins, Inc. v. Multivision Cable TV Corp*., 789 F. Supp. 760, 777 (S.D. Miss. 1992) (citing *Int'l Distrib. Ctrs. v. Walsh Trucking Co*., 812 F.2d 786, 793 (2d Cir. 1987), cert. denied, 482 U.S. 915(1987)), *aff'd sub nom*. *Futurevision Cable v. Multivision*, 986 F.2d 1418 (5th Cir. 1993). Spring cannot make out a conspiracy claim and so it certainly cannot make out a specific intent claim.

> defendants] is that each one of them, acting on its own, signed a bilateral dealing agreement with [primary defendant]. The only plausible inference from that conduct is that each Dealer sought to acquire, retain and/or increase its own business. *Significantly, the antitrust laws do not prohibit such conduct*.

Dentsply, 602 F.3d at 258 (emphasis added); *see also Syufy Enters. v. Am. Multicinema, Inc.*, 793 F.2d 990, 1000 (9th Cir. 1986) ("Supplier who licenses a product to another does not join the licensee in a conspiracy" even if "the licensee turns around and exploits the license for its own monopolistic purposes."); *Futurevision Cable Sys.*, 789 F. Supp. at 778 ("The bare fact that ESPN and The Learning Channel granted exclusive licenses to Multivision and B & E does not provide a sufficient basis to infer that ESPN and The Learning Channel were parties to an intentional conspiracy to monopolize either B & E's or Multivision's markets.").

Spring's conspiracy claims must fail.

D. Spring's State Law Claim Fails.

Spring repackages its antitrust claims under an unfair competition label in an attempt to shoehorn a claim under Pennsylvania common law for unfair competition. (*See* Am. Compl. ¶¶ 162-66 (Count IV)). It does so because Pennsylvania does not have an antitrust statute and "[n]o court to date has held that a private remedy is available for damages under Pennsylvania's common law on antitrust violations." *XF Enters., Inc. v. BASF Corp*., 47 Pa. D. & C.4th 147, 150 (Com. Pl. 2000); *see also Stutzle v. Rhone-Poulenc S.A*., 2003 WL 22250424 at *1 (Pa. Com. Pl. 2003) (same); *Lakeview Ambulance and Med. Servs., Inc. v. Gold Cross Ambulance and Med. Servs., Inc.*, 1995 WL 842000 at *4 (Pa. Com. Pl. 1995) (same). "Numerous federal courts have followed this guidance, disallowing claims for damages under Pennsylvania common law for antitrust violations to proceed." *Presque Isle Colon & Rectal Surgery v. Highmark Health*, 391 F. Supp. 3d 485, 504 (W.D. Pa. 2019) (compiling cases).

Causes of action for unfair competition are not meant to address anticompetitive concerns,

especially such as those Spring asserts here. *Lakeview Ambulance*, 1995 WL 842000 at *2 ("[U]nfair competition does not extend to discouragement of setting up competitive businesses where there is no appreciable deception intended to confuse one's goods for another's goods."). Aware of these obvious shortcomings, Spring manufactures its own standard for unfair competition by conjuring amorphous "standards of commercial morality" and "accepted principles of public policy." (Am. Compl. ¶ 164). In addition to being hopelessly unsupported, these claims have no basis whatsoever in Pennsylvania statutory or common law.[28]

Even if Spring's claims were recognized under Pennsylvania's common law, they would fail for the same reasons its federal claims fail. *Fresh Made, Inc. v. Lifeway Foods, Inc.*, 2002 WL 31246922 at *9 (E.D. Pa. 2002) (dismissing state law allegations of unfair competition that "essentially mirror" Sherman Act claims"). Spring's state law claims should be dismissed.

CONCLUSION

For all the foregoing reasons, Retrophin respectfully asks the Court to dismiss the Complaint with prejudice. Retrophin requests oral argument to the extent it would assist the Court in analyzing and deciding this motion.

[28] Pennsylvania appears to only apply the standard of "commercial morality" to appropriation of trade secrets through improper means, for example, through the use of "misrepresentations and espionage." *Coll. Watercolor Grp., Inc. v. William H. Newbauer, Inc.*, 468 Pa. 103, 114 (Pa. 1976).

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on April 1, 2020 I filed this document on the Court's docket using the Court's CM/ECF system. Based on the Court's records, all counsel of record were served with a copy of the foregoing document by electronic means.

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